## The Solae<sup>©</sup> Company.

Patricia Daniels, Director Supplemental Food Programs Division FNS, USDA 3101 Park Center Drive Room 520 Alexandria, VA 22302

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Comments on RIN 0584-AD39 Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions to the WIC Food Packages

The Solae Company supports the WIC Program and its goal of providing essential nutrients for low-income children as well as pregnant, breastfeeding and non-breastfeeding mothers. The Solae Company, based in St. Louis, Missouri, is an ingredient provider that serves the food and beverage manufacturers, retailers and consumers in 80 countries worldwide. For more than 30 years, The Solae Company (an innovative venture between DuPont and Bunge, Ltd.) has invested in fundamental research to further understand the real health benefits of soy protein. As the science behind the food provided by the WIC program is evaluated by USDA Food and Nutrition Service (FNS) and the Institute of Medicine (IOM) Food and Nutrition Board (FNB), The Solae Company appreciates the opportunity to recommend modifications to the types of foods included in the WIC program.

In general, The Solae Company recommends:

- 1. We support the continued offering of soy infant formula in the WIC program.
- WIC should consider more alternative foods in each core food package to select as sources of essential nutrients.
- The food packages should be designed to address serious health conditions in children, such as overweight and obesity, high blood pressure, diabetes, cardiovascular disease.
- 4. Because the WIC program serves a low-income population where minority groups including African American, Hispanic/Latino American, Asian American, Pacific Islander, and American Indian and Alaskan Natives are disproportionately represented, the opportunity exists for the program to expand its food choices to include low-fat, low-sodium soy products that contain iron, calcium, high-quality protein, and no saturated fat.

## Which elements of the WIC food package should be kept the same?

We support the continued offering of soy infant formula in the WIC program.
 Soy-based infant formula is a healthy choice for full-term infants when mothers cannot or choose not to breast feed. In the US, soy-based infant formula accounts for 20-25% of formula sales. The incidence of milk protein allergy is estimated to be between 1 and 7.5% of infants. Additionally, 1 to 3% of babies are born



without the ability to digest lactose. The American Academy of Pediatrics endorses the use of soy-based infant formula, and the Food and Drug Administration has determined it is a safe and acceptable infant feeding formula. Particularly for infants suffering from milk allergies or lactose intolerance, soy-based infant formula is a very healthy choice.

What changes, if any, are needed to the types of foods currently authorized in the WIC food packages?

The Solae Company recommends that the Department and IOM investigate the opportunity for WIC directors to have more alternative foods in each core food package to select as sources of essential nutrients.

• The Solae Company believes in the importance of having foods that are nutritionally and culturally appropriate available to WIC participants. In the twenty-three years since the WIC packages were designed, the country has experienced dramatic changes in population demographics in terms of ethnic and racial diversity. Lactose intolerance is prevalent in some population groups as early as two years of age. Studies have found the following prevalence rates:

African Americans: up to 72% of school aged children

Hispanic Americans: up to 56% of school aged children

Native Americans: up to 70% of school aged children

Asian Americans: up to 85% of school aged children

Caucasian Americans:up to 21% of school aged children

- In addition, over that same time period, hundreds of research studies have shown that soy protein may provide certain health benefits. For instance, epidemiological evidence demonstrates that consumption of soy foods may be associated with a lower risk of certain cancers - including breast cancer - in Asian countries. The death rates for breast cancer are 2 ½ times higher in American women than in Japanese women. In searching for an explanation for this difference, scientists found that Asian diets tend to be higher in protein from soybeans and other plant sources. Studies also have found that soy consumption during adolescence results in a significant reduction in the risk of breast cancer later in life, in both pre-menopausal and post-menopausal women. Because of this research, awareness of the health benefits of soy protein has increased among consumers and demand has increased for soy based products. Therefore, we encourage USDA and IOM to consider recent national trends in the popularity, acceptance, and consumption of soy protein based foods and studies documenting the health benefits of soyfoods for both adults and children, in making decisions about what foods should be added to the WIC food package.
- USDA and IOM may also want to consider establishing new criteria for foods to include in the WIC package to correspond more closely with *Healthy People 2010* goals. The *Healthy People 2010* report has identified the elimination of health disparities as one of its two overarching goals. According to the DHHS *Healthy*

People 2010 report "overweight and obesity are observed in all population groups, but obesity is particularly common among Hispanic, African American, Native American, and Pacific Islander women." The Healthy People 2010 goals outlined for nutrition include decreasing total fat, saturated fat, and sodium and increasing calcium and iron intake. Because the WIC program serves a low-income population where minority groups including African American, Hispanic/Latino American, Asian American, Pacific Islander, and American Indian and Alaskan Natives are disproportionately represented, the opportunity exists for the program to expand its food choices to include low-fat, low-sodium soy products that contain iron, calcium, high-quality protein, and no saturated fat. Allowing the choice of soy protein based foods including soymilks, tofu and soy based cheeses would empower WIC clients—who are at higher risk for obesity and related co-morbidities than the general population—to make healthy food choices consistent with Healthy People 2010 goals.

### Should the quantities of foods in the current WIC food packages be adjusted?

The 1999 Review of the Nutritional Status of WIC Participants did not consider saturated fat, total fat or total calories among the target nutrients/nutrients of concern, and thus these components were not presented in the nutritional analysis. However, Chart 3 detailing the nutritional content of current food WIC provided foods in Federal Register/Vol. 68, No. 178/Monday, September 15, 2003 indicates that the various packages can provide between 17.9 and 23.8 grams of saturated fat per day. Based on a 2,000 kcal diet, the WIC food packages can easily meet or exceed the recommended limit for saturated fat (<10% of total calories). The high saturated fat content of the provided food is especially of concern given that WIC foods are designed to be supplementary to the normal diet which most likely contains saturated fat as well.

- We urge the USDA and technical experts on the Institute of Medicine's Food and Nutrition Board to review current data available from nutrition surveys of the WIC population and national nutrition monitoring surveys (NHANES/CSFII) to determine the appropriateness of the current quantities of saturated fat, total fat, total calories, and sodium consumed in the American diet and provided via the various WIC food packages.
- USDA and IOM should also consider recommending that WIC nutritional advice emphasize the importance of total calorie intake and physical activity in weight maintenance as well as the health benefits of lowering saturated fat intake for both mothers and children.

Can the WIC food packages be revised to have a positive effect on addressing overweight concerns?

 Obesity is a very serious health concern because it puts people at a greater risk of developing conditions such as high blood pressure, diabetes, cardiovascular disease, stroke, and cancer. Many of these conditions can be life threatening. Because obesity and overweight are the number one nutritional problems in children in the U.S., the WIC program should include foods that help combat this issue. The prevalence of obesity and overweight is growing in children ages 1-5 (WIC coverage age) as well. Adding soyfoods to the diets of children can have a positive impact on a child's weight. Protein is associated with greater satiety and may help children better control their appetite over the course of the day.

- The National Institutes of Health, the National Heart, Blood and Lung Institute, and the North American Association for the Study of Obesity recommend that diets for weight loss should contain plant-based and lean animal protein.
  - O As a nutritionally rich plant-based protein, soy fits well with this recommendation.
  - O Soy protein contains no saturated fat and cholesterol associated with many dietary sources of animal protein.
  - O Soy protein is a complete, high-quality protein equal to that of milk, eggs and meat.

Atherosclerosis is a common co-morbidity of overweight and obesity that has been documented even in young children. Research related to soy protein and heart disease prevention should be reviewed and soy protein should be considered as a possible healthy alternative to provide protein and calcium in the WIC packages.

• The above information for added physical activity will aid this component as well.

Are there other concerns that affect foods issued through the WIC food packages that should be considered in designing the food packages?

- We suggest USDA and the IOM panel consider the cultural appropriateness of the WIC food packages. Considering that some minority groups are low consumers of dairy, especially Asian Americans and African Americans, it may be desirable to offer recipients several non-dairy sources of calcium.
- Over the years, the number of Americans seeking soyfoods has increased dramatically. Soymilk sales have grown from \$100 million in 1995 to nearly \$600 million in 2002. Tofu sales have grown from \$108 million in 1992 to \$250 million in 2002<sup>i</sup>. According to the United Soybean Board's 2003-2004 Consumer Attitudes Report, regular usage of soymilk increased from 14% to 17% in 2003<sup>ii</sup>. These trends clearly indicate the increasing interest in consuming soy by the American public. If the WIC program is to continue to be regarded as a health resource by the public, available foods must evolve to reflect current nutrition knowledge about health promoting foods and to meet changing consumer expectations.

- Cow's milk allergy is estimated to affect between 2% and 5% of all infants and children, minority and majority. USDA and the IOM panel may consider reviewing the research on cow's milk and egg allergies to determine if offering soy-based alternatives would likely increase the positive nutritional impact of the program.
- The panel should consider the feasibility of adding alternatives to dairy foods and allow WIC nutritionists to decide which products to offer their WIC participants.

How can WIC food packages best be designed to effectively meet nutritional needs in culturally and ethnically diverse communities?

Considering that there are groups of WIC recipients who are still not meeting their daily requirement for calcium, any changes to the food packages that provide for flexibility in choosing ones own calcium source could be expected to improve calcium intake among the WIC population.

- USDA and IOM should review the CSFII data to determine the current sources of
  calcium and levels of dairy consumption based on income and ethnicity. CSFII
  data is currently only available for African Americans, Mexican Americans,
  Non-Hispanic White Americans, and Other Hispanic Americans.
- USDA and IOM may consider commissioning focus groups and surveys of groups who may be underrepresented in national dietary surveys to better understand cultural food practices, opinions of different racial and ethnic groups toward the currently available WIC packages, and suggestions for improving the cultural appropriateness of the WIC food packages.

<u>Identify/recommend WIC food selection criteria, describe how the criteria interact, indicate their relative weighting or importance.</u>

- Foods must provide key nutrients determined to be lacking in the diets of WIC
  participants as indicated by national and targeted surveys of the WIC eligible
  population.
- 2. A reasonable effort should be made to ensure that WIC foods within each of the categories of key nutrients are regularly consumed by each of the racial and ethnic groups represented within the WIC population and address barriers to nutrient intake such as intolerance and allergy. If data for specific racial and/or ethnic groups is not available from national nutrition monitoring surveys, focus groups and other survey methods can be used to determine preferences of the population.
- 3. Efforts to limit the fat and saturated fat of WIC food should be pursued. Upper limits of some nutrients such as total fat and saturated fat should be established.
- 4. Cost-effectiveness of delivering key nutrients should also be considered when selecting foods for the WIC food package.

# What data and/or information should the Department consider in making decisions regarding revisions to the WIC food packages?

The Department and the IOM/FNB should consider the following studies:

#### Heart Health

• In order for the FDA to approve the soy and heart disease health claim, hundreds of studies on soy were reviewed. This extensive review confirmed the health and safety of soy and the ability of soy protein to have a positive effect on heart health. Food and Drug Administration. Food Labeling: health claims; soy protein and coronary heart disease. Fed Reg Oct 26, 1999;64(206) [21 CFR Part 101].

#### Iron Bioavailability

• A recent study of women with marginal iron deficiency showed that iron from soybeans was well absorbed. The absorption was measured at 27% and the authors concluded that soybeans appear to be a good source of nutritional iron in marginally iron-deficient individuals. Murray-Kolb LE, Welch R, Theil EC, Beard JL. Women with low iron stores absorb iron from soybeans. Am J Clin Nutr. 2003 Jan;77(1):180-4. <a href="http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=12499339&dopt=Abstract">http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=12499339&dopt=Abstract</a>

#### **Breast Cancer**

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• Researchers conducted a population-based, case-control study of breast cancer among Chinese, Japanese and Filipino women in Los Angeles County to further investigate the role of soy. During 1995-1998, 501 breast cancer patients and 594 control subjects were interviewed. The researchers found higher soy intake in childhood in Asian-Americans is associated with reduced breast cancer risk. Risk may be further reduced by intake as an adult. Wu AH, Wan P, Hankin J, Tseng CC, Yu MC, Pike MC. Adolescent and adult soy intake and risk of breast cancer in Asian-Americans. Carcinogenesis. 2002 Sep;23(9):1491-6. <a href="http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=12189192">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=12189192</a>

This study analyzed data from a population-based case-control study of 1459 breast cancer cases and 1556 age-matched controls to explore the link between soyfood intake during adolescence and development of breast cancer. The researcher's results suggest that soy intake during adolescence may reduce the risk of breast cancer in later life. Developing eating habits that include soyfoods as a young child should facilitate more healthful eating patterns through adolescence and adulthood. Shu XO, Jin F, Dai Q, Wen W, Potter JD, Kushi LH, Ruan Z, Gao YT, Zheng W. Soyfood intake during adolescence and subsequent risk of breast cancer among Chinese women. Cancer Epidemiol Biomarkers Prev. 2001 May;10(5):483-8. <a href="http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=11352858&dopt=Abstract">http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=11352858&dopt=Abstract</a>

• It has been documented that the addition of soy protein to school lunchmeats and other meal items can reduce the fat and saturated fat content of the meals.

Thomas JM, Lutz SF. Soy protein lowers fat and saturated fat in school lunch beef and pork entrees. J Am Diet Assoc. 2001 Apr;101(4):461-3. <a href="http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=1">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=1</a> 1320954&dopt=Abstract

#### Milk Allergy

This study documents the prevalence and clinical symptoms of cow's milk allergy.
 Moneret-Vautrin DA. Cow's milk allergy. Allerg Immunol (Paris). 1999 Jun;31(6):201-10.
 <a href="http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=10443301">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=10443301</a>
 &dopt=Abstract

#### Satiety and Weight Management

• This article reviews higher protein diets and the satiety and appetite control associated with adding protein to the diet.

Eisenstein J, Roberts SB, Dallal G, Saltzman E. High-protein weight-loss diets: are they safe and do they work? A review of the experimental and epidemiologic data. *Nutr Rev* 2002, 60:189-200.

#### Acceptance of Soy

• Dr. J. Enders evaluated acceptance of soy-enhanced lunches compared with traditional menus by preschool children. Soy-enhanced foods were substituted on a traditional cycle menu, and the amount eaten, energy, and nutrient values for traditional and soy-enhanced lunches were compared. The researchers concluded that preschool programs can substitute soy-enhanced menus for traditional foods and add variety to the diet without sacrificing taste, energy, or nutrient value. Endres J, Barter S, Theodora P, Welch P. Soy-enhanced lunch acceptance by preschoolers. J Am Diet Assoc. 2003 Mar;103(3):346-51. <a href="http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=12616257">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\_uids=12616257</a> &dopt=Abstract

Thank you for the opportunity to provide suggestions for improvement of the WIC food package. If you have questions regarding our comments, please contact Geri Berdak, Director of Public Affairs, at (314) 982-2588.

<sup>&</sup>lt;sup>i</sup> Soyfoods 2003 & Beyond: Global & U.S. Perspectives, speech presented by Peter Golbitz, Soyatech, at the 11th USB/SANA Soy Symposium, Chicago, October, 2003.

<sup>&</sup>lt;sup>ii</sup> United Soybean Board. Consumer Attitudes About Nutrition. Annual report 2003-2004. Accessed at www.talksoy.com 11/14/03.